



DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION, FIELD OPERATIONS BRANCH, COMPLIANCE TEAM

d11653b 141-1-50

4298 Elysian Fields Avenue
New Orleans, LA 70122
Telephone (504) 589-7166
Fax (504) 589-4657

April 13, 1998

WARNING LETTER NO. 98-NOL-18

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. William T. Bergeron, President
Gulf Coast Dockside, Inc.
P.O. Box 26395
New Orleans, LA 70186

Dear Mr. Bergeron:

A Food and Drug Administration (FDA) investigator performed an inspection of the vessel watering point at Gulf Coast Dockside, Inc., #1 Elaine Street, New Orleans, Louisiana on April 2, 1998. The observations made during the inspection are in violation of the Public Health Service Act and the Food Drug and Cosmetic Act as promulgated in Title 21, *Code of Federal Regulations*, Parts 1240 and 1250.

During the inspection, the following violations were noted:

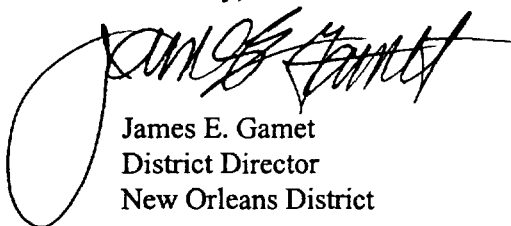
- 1) Neither potable nor non-potable outlets, on any of eleven dual use hydrants, had backflow protection devices installed;
- 2) Potable and non-potable outlets, on the same line, did not have those for non-potable use identified as such;
- 3) There were no cap and keeper chains on any of the potable water outlets.

The list of inspectional observations, identified above, is not intended to be an all-inclusive list of the conditions observed at your facility. It is your responsibility to assure adherence with all requirements of the regulations.

Based on the inspectional findings, we are classifying your facility as **PROVISIONAL** for interstate carrier use for a period of thirty (30) days. "Provisional" means that the facility may continue to operate; however, significant correction of violations must be made by the expiration date. On or about that date, a reinspection of this facility will be conducted to assure that corrections meet FDA requirements. If significant corrections are not made by the time of the next inspection, the facility will be reclassified as NON-APPROVED for carrier use.

Please advise this office within fifteen (15) days of the receipt of this letter regarding the measures you have implemented to correct the violations and to assure that such violations will not recur. Your response should include a discussion of delays you foresee in achieving correction, and a deadline by which correction can be expected. Your response should be directed to Nicole F. Hardin, Compliance Officer, U.S. Food and Drug Administration, 4298 Elysian Fields Avenue, New Orleans, Louisiana 70122-3896.

Sincerely,

A handwritten signature in black ink, appearing to read "James E. Gamet", is written over a large, stylized, handwritten letter "J" that serves as a flourish or initial.

James E. Gamet
District Director
New Orleans District

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Enclosure: FDA-483